



Colorado Center for
BONE RESEARCH

Osteoporosis Medications

When does a doctor prescribe osteoporosis medications?

Healthcare providers look at several pieces of information before prescribing a bone-preserving or bone-building medication. This includes your risk factors for osteoporosis, your risk for fracture, your medical history, your current health and your bone mineral density (BMD) test results.

Bone density is determined by a quick and painless dual-energy x-ray absorptiometry (DXA) scan of the hips and spine – the bones most likely to break due to osteoporosis. The results of your DXA scan will show a T-score for each bone that is tested. A T-score compares the strength of a person's bones with the peak bone mass of young adults.

If bone density is **normal**, the T-score will be at or above -1. Most people with normal bone density don't need to take an osteoporosis medicine.

A T-score ranging from 1/1/ to 12/4 indicates **low bone density** (also called osteopenia). People with low bone density are more likely to get osteoporosis. They should consider taking an osteoporosis medicine when they have certain risk factors that suggest an increase chance of breaking a bone.

Healthcare providers can use a Web-based tool called FRAX to figure out a person's risk for breaking a hip or other major bone within the next 10 years. This information will help you and your provider decide whether you should start taking an osteoporosis medication.

Osteoporosis is diagnosed if the T-score is -2.5 or lower. All people with osteoporosis should consider taking an osteoporosis medication

People who have broken a hip or bones in the spine should consider taking an osteoporosis medication.

What to Consider When Choosing a Medicine

There is a lot to think about when choosing an osteoporosis medication. You and your healthcare provider may want to look at:

Your gender. While all osteoporosis medications are approved for women, only four are approved for men. The ones approved for men are Alendronate (Fosamax), Risedronate (Actonel), teriparatide (Forteo) and Zoledronic acid (Reclast).

Your age. Some medications may be more appropriate for women who have recently gone through menopause, while others are more appropriate for older women. You should talk to your healthcare provider about what medicine is best for you at this time.

If you have not reached menopause. Most of the osteoporosis medications are not approved for premenopausal women. But, three osteoporosis medications are approved for the prevention or treatment of osteoporosis in premenopausal women as a result of taking steroid medications for a long time. In very rare cases, a healthcare provider may recommend that a premenopausal woman consider taking an osteoporosis medicine for other reasons, like severe bone loss due to a medical condition, or breaking a bone because of low bone density.

How severe your osteoporosis is. Osteoporosis medications work in different ways. A person with more severe bone loss or a broken bone may take a different medicine than a person with only minor bone loss.

Other health problems you may have. Your healthcare provider will consider other health problems you have when recommending a medicine. If you have had breast cancer or blood clots, for example, you should not take estrogen or Raloxifene (Evista). If you've had radiation treatment involving your bones, you should not take teriparatide (Forteo).

Personal preference. Do you prefer a pill, liquid or intravenous (IV) medicine, or one that is given as a nasal spray or an injection? Does it work better for you to take your medicine every day, once a week, once a month, several times a year or even once a year? Any of these could influence your treatment decision.

Keep in mind that how well a medication works, or what side effects it may have, will not be the same

Medicines to Prevent or Treat Osteoporosis

The U.S. Food and Drug Administration (FDA) has approved a number of medications to prevent or treat osteoporosis. There are two main types:

Antiresorptives. In the bone remodeling cycle, antiresorptive medications slow the breakdown of bone. This helps prevent bone loss. When you first start taking these medications, you stop breaking down bone as quickly as you did before, but you still make new bone at a normal rate. So,

your bone density might even increase. These medications also lower your risk of breaking bones. The antiresorptives are:

- Bisphosphonates
- Calcitonins
- Estrogen agonists/antagonists
- Estrogen therapy (ET) and hormone therapy (HT)

Anabolics. In the bone remodeling cycle, anabolic medications help your body make new bone more quickly. They increase your bone density and lower your risk of breaking bones. Only one type of anabolic medicine has been approved for osteoporosis:

- Parathyroid hormone

Class	Drug	Brand Name	Form	Frequency
Antiresorptives	Bisphosphonates			
	Alendronate	Generic Alendronate and Fosamax	Oral (tablet)	Daily/Weekly
	Alendronate	Fosamax Plus D (with 2,800 IU or 5,600 IU of Vitamin D ₃)	Oral (tablet)	Weekly
	Alendronate	Fosamax	Oral (liquid solution)	Weekly
	Ibandronate	Boniva	Oral tablet	Monthly
	Ibandronate	Boniva	Intravenous (IV) injection	Four Times per Year
	Risedronate	Actonel	Oral (tablet)	Daily/Weekly/Twice Monthly/Monthly
	Risedronate	Actonel with Calcium	Oral (tablet)	Weekly
	Zoledronic Acid	Reclast	Intravenous (IV) infusion	One Time per Year
	Calcitonins			
	Calcitonin	Fortical	Nasal spray	Daily
	Calcitonin	Miacalcin	Nasal spray	Daily
	Calcitonin	Miacalcin	Injection	Varies
	Estrogen Agonist/Antagonists			
	Raloxifene	Evista	Oral (tablet)	Daily

Estrogen Therapy (ET) and Hormone Therapy (HT)*				
	Estrogen	Multiple Brands	Oral (tablet)	Daily
	Estrogen	Multiple Brands	Transdermal (skin patch)	Twice Weekly/ Weekly
Parathyroid Hormone				
Anabolics	Teriparatide	Forteo	Subcutaneous injection (under the skin)	Daily

Antiresorptive Medicines

Antiresorptive medicines slow the breakdown of bone. The following information is about the four types of antiresorptive medications.

Bisphosphonates

There are four bisphosphonate medications available. They are:

- Alendronate (Fosamax), also available as a generic medication
- Ibandronate (Boniva)
- Risedronate (Actonel)
- Zoledronic acid (Reclast)



The bisphosphonates can increase bone density.

They can lower the risk of breaking bones in the spine. Alendronate, Risedronate and Zoledronic acid lower the risk of breaking a hip and other bones. For people who have recently broken a hip, Zoledronic acid lowers the risk of new broken bones.

All four bisphosphonate medications are approved for postmenopausal women. Alendronate, Risedronate and Zoledronic acid are approved for men. Ibandronate is for women only. Some bisphosphonates are for both the prevention and treatment of osteoporosis and others are for treatment only.

For women and men, Risedronate and Zoledronic acid are also approved to prevent and treat osteoporosis caused by taking steroid medications, such as cortisone and prednisone. Alendronate is approved to treat osteoporosis caused by these medicines.

How to take bisphosphonates. Bisphosphonates are available in the following forms:

- **Tablets.** Alendronate, Ibandronate and Risedronate are available as tablets taken either once a day, once a week, twice a month or once a month. You take one table first thing in

the morning after waking up and on an empty stomach. The tablet must be swallowed whole with 6 to 8 ounces of plain water (no other liquid), at least 30 minutes before having anything to eat or drink. When you take an Ibandronate tablet, you need to wait at least 60 minutes before eating or drinking. You must remain upright (sitting, standing or walking) during this 30-minute or 60 minute period.

For Actonel with calcium, the weekly Actonel tablet is available with separate calcium carbonate tablets. The calcium table is **not** taken at the same time as the Actonel tablet because calcium prevents the absorption and activity of Actonel.

For Fosamax Plus D, the Weekly Fosamax tablet contains both Alendronate and vitamin D. The vitamin D is not in a separate tablet or capsule.

- **Liquid.** Alendronate is also available as a liquid (oral) solution. This oral solution is taken one a week, first thing in the morning on an empty stomach. You need to drink the entire bottle of solution. Right after you drink the solution, you must drink at least 2 ounces of plain water. After drinking the solution and 2 ounces of plain water, you must remain upright (sitting, standing or walking) for at least 30 minutes with no food or drink during that time.
- **Intravenous (IV).** Ibandronate is available as an intravenous (IV) injection given every tree months. A healthcare professional give the IV injection in a doctor's office or other outpatient setting. It takes less than a minute to inject the medicine. You should have a blood test to check your kidneys before each IV injection. Some healthcare providers may also check blood calcium and vitamin D levels.

Zoldronic acid is the first and only once-a-year osteoporosis medication. A healthcare professional gives zoledronic acid as an intravenous (IV) infusion in a doctor's office or other outpatient setting. It takes at least 15 minutes for the yearly infusion. You should eat as you normally would, but you need to drink two glasses of water or another liquid within a few hours before receiving zoledronic acid. You will need to have two bold tests before each IV dose. One is a test to check your kidneys. The other is a test to check calcium and possibly other mineral levels in the blood.

Side effects of bisphosphonates. Bisphosphonates are not recommended for people with severe kidney disease or low blood calcium. People with certain problems of the esophagus may not be able to take the oral tablets. The esophagus is the tube that connects the throat to the stomach.

The side effects of **all bisphosphonates** can include bone, joint and muscle pain. Eye inflammation and osteonecrosis of the jaw (ONJ) are rare side effects of all bisphosphonate medications.

The more common side effects of **bisphosphonates taken as a tablet or liquid** include problems with the digestive system, such as trouble swallowing, heartburn and irritation of the esophagus.

Side effects can occur shortly after receiving IV bisphosphonates including flu-like symptoms, fever and headaches. These generally stop within two or



three days and usually only happen after the first IV infusion. To help prevent or relieve these symptoms, patients may be given acetaminophen or another over-the-counter medication either before or after the IV infusion.

Special concerns about bisphosphonates. Many authorities recognize that certain serious conditions with bisphosphonate medications may cause concern for people taking them. There have been reports of atrial fibrillation, osteonecrosis of the jaw (ONJ), severe pain and unusual broken bones in the thigh. While these conditions are serious, the number of people affected remains extremely small compared to the number of people who have taken these medications. It is not yet known whether the medications are truly causing these problems, in part because the problems are so rare.

Based on information that is currently available, authorities believe that for most people taking bisphosphonate medication, the benefits outweigh the risks of developing one of these unusual but serious conditions. These medications play an important role in stopping bone loss and preventing broken bones. You should discuss your concerns about these possible side effects with your healthcare provider.

Calcitonins

Calcitonin is a hormone that affects calcium and bone. Calcitonin medications are approved to treat osteoporosis in women who are at least five years past menopause. These medications are available as either Fortical or Miacalcin.

Calcitonins can increase bone density in the spine. They lower the risk of breaking bones in the spine, but they do not lower the risk of breaking a hip or other bones.

How to take calcitonins. Both Fortical and Miacalcin are available as a spray used in the nose. The nasal spray is usually used one a day, with the patient switching nostrils every day. Miacalcin is also available as an injection. It is given under the skin or into a muscle, usually once a day or once every other day.

Side effects of calcitonins. Common side effects with nasal calcitonin are runny nose, headache, back pain and nosebleeds. Injectable calcitonin may cause an allergic reaction and unpleasant side effects, such as flushing of the face and hands, needing to urinate often, nausea and a skin rash.

Estrogen Agonists/Antagonists

Estrogen agonists/antagonists are for postmenopausal women only. They used to be called selective estrogen receptor modulators (SERMs). They are developed to provide the benefits of estrogen therapy without the risks. They are not hormone or estrogen.



The only estrogen agonist/antagonist approved to prevent or treat osteoporosis is Raloxifene (Evista). It can increase bone density. While it lowers the risk of breaking bones in the spine, the studies so far do not show that it lowers the risk of breaking a hip and other bones.

Studies show that Raloxifene decreases the risk of the most common type of breast cancer that occurs in postmenopausal women. The FDA has approved it to decrease the risk of breast cancer in women with osteoporosis and even in women without osteoporosis who are at high risk of breast cancer.

How to take estrogen agonists/antagonists. For both the prevention and treatment of osteoporosis, raloxifene is taken every day as a tablet with or without meals.

Side effects of estrogen agonists/antagonists. Side effects with Raloxifene can include blood clots, hot flashes and leg cramps. Other side effects include swelling and temporary flu-like symptoms. Raloxifene is not associated with problems of the uterus or ovaries and does not affect cognitive (mental) function. Because this medicine can cause hot flashes, it may not be the best choice for women who have recently gone through menopause and are still having menopausal symptoms.



Women who have had blood clots or breast cancer should not take this medication. They should also not take it if they have and increased risk for stroke. This includes women who:

- Have already had a stroke
- Have transient ischemic attacks (TIAs), which are sometimes called “mini strokes” and can come and go quickly
- Have atrial fibrillation, which is a type of serious irregular heart beat
- Have uncontrolled high blood pressure
- Are smokers

Estrogen Therapy (ET) and Hormone Therapy (HT)

Estrogen therapy (ET) and hormone therapy for (HT) are for women only. The terms refer to therapy with estrogen alone (ET) and estrogen given with progesterone (HT). ET and HT are approved to prevent osteoporosis in postmenopausal women. Estrogen is a hormone that protects bone. It can increase bone density. It lowers the risk of breaking bones in the spine and breaking a hip and other bones. ET and HT also help relieve menopausal symptoms. Many brands and generic forms are available.

How to take ER and HT. ET and HT are available as a tablet or skin (transdermal) patch and in other forms. Estrogen and hormone medications come in many different doses.

Side effects of ER and HT. Taking estrogen by itself increases a woman's risk for uterine cancer. To reduce this risk, women with a uterus are given estrogen with progesterone (HT). Estrogen alone (ET) is given to women who have had their uterus removed. Side effects may include vaginal bleeding, breast tenderness and gallbladder disease.

Although estrogen can reduce bone loss, large studies have found that it also slightly increases a woman's risk of stroke, blood clots, breast cancer and other problems. As a result, the FDA recommends that if you need a medication for osteoporosis you look at other medications before taking ET or HT. Because ER and HT can have serious risks, you should take to your healthcare provider to see if the benefits outweigh the risks. If you decide to take ER or HT, you should take the lowest possible dose for the shortest period of time.

Special Concerns About ET and HT

The Woman's Health Initiative (WHI) study found that one type of HT called Prempro reduced the risk of breaking a hip and other bones and reduced the risk of getting colon cancer. In the study, it was given to women who on average were more than 10 years past menopause. It was associated with a slight increase in the risk of breast cancer, strokes, heart attacks, blood clots and cognitive (mental) decline. Although ET was associated with a similar increase in the risk of strokes, blood clots and mental decline, it did not increase the risk of breast cancer or heart attacks. Recent studies suggest that the risks of HT may be lower in women closer to menopause.



Anabolic Medicines

Anabolic medicines help build new bone. The following information is about the one type of anabolic medicine.

Parathyroid Hormone

Teriparatide (Forteo) is a type of parathyroid hormone. It is the only anabolic or bone-building medicine currently approved for osteoporosis. The FDA has approved it to treat osteoporosis in postmenopausal women and in men.

Teriparatide lowers the risk of breaking bones in the spine and breaking other bones. This medication builds new bone and greatly increases bone density, especially in the spine.

You may consider taking teriparatide if you have broken a bone due to osteoporosis and have very low bone density, such as a T-score lower than -3.0. Teriparatide may also be a choice if you continue to lose bone density or break a bone while being treated with another osteoporosis medication.

How to take parathyroid hormone. Teriparatide is given by a daily self-injection. The FDA has approved its use for up to two years only. At the end of two years, to retain the benefits of treatment with teriparatide, most experts recommend that patients start an antiresorptive medicine. This is usually a bisphosphonate.

Side effects of parathyroid hormone. Side effects can include leg cramps in the blood and urine can occur, but this medicine does not increase the risk of kidney stones.

People with certain conditions should not take this medication. This includes people with Paget's disease of bone and people who have had radiation treatment that involved the bones. It also should not be given to people with metabolic bone diseases such as hyperparathyroidism and those with cancer that has spread to bone. Also, people who have certain abnormal blood tests, including increased calcium levels, should not take this medicine.

Reporting Side Effects

If you think you're having a side effect from your medicine, it's important to tell your healthcare provider. For serious reactions or problems with a drug, either you or your healthcare provider should report the problem to the U.S. Food and Drug Administration (FDA). The toll-free number for the FDA is (800)332-1088. You can also complete a report online by visiting the FDA Web site at www.fda.gov/medwatch.

You may also want to report serious side effects and problems to the company that makes the medicine. The chart below provides the phone numbers of these companies and the date each medicine was approved by the FDA as an osteoporosis medicine.



Special Concerns about parathyroid hormone. In rat studies, the drug was given in very high doses over a long period of time and caused a rare bone cancer. This has not been seen in humans. There has been no evidence of an increased risk of this cancer in humans taking teriparatide.

Taking Two Medications at the Same Time

Sometimes healthcare providers recommend taking two different osteoporosis medications at the same time. This usually means taking a bisphosphonate and a medication that is not a bisphosphonate. Taking two osteoporosis medications at the same time may provide a small increase in bone density compared to only taking one. It is not known if this provides greater protection from breaking bones. Also, it's possible that taking two medications may cause more side effects. If your healthcare provider suggests adding a second medicine, you will need to decide if the possible gains are worth the added cost and possible side effects.

What to Expect From Your Medication

With antiresorptive medications, the goal of treatment is to prevent more bone loss and reduce the risk of breaking bones in the future. Response to treatment with these medications is considered well if:

- Your bone density stays the same
- You don't break any bones

With the one anabolic medication, the goal of treatment is to build new bone, increase bone density, repair tiny defects in bone and reduce the risk of breaking bones. Response to treatment is considered good if:

- Your rate of making new bone increases
- Your bone density improves
- You don't break any bones

Staying With Your Treatment Plan

When you take an osteoporosis medication, you will not feel your bones getting stronger. This can make it hard to stay on a treatment plan. But, it's important to take your medication if you want it to work. You should take it just as your healthcare provider prescribed it, and you must remember to take it. When you have questions about your medications, be sure to speak with your healthcare provider or pharmacist.

If you decide that a treatment is not right for you, don't just stop taking the medication. First talk with your healthcare provider about your concerns. When prescriptions are filled, or if they are forgotten, taken incorrectly or stopped early, your health condition may not improve and could get worse. Your healthcare provider may find it difficult to figure out why you aren't getting better. This can lead to extra tests, prescriptions, costs and broken bones that could have been prevented by taking the medication as directed.



How to Know If Your Medication Is Working

To find out how well your treatment is working, your healthcare provider might repeat your bone mineral density (BMD) test every two years. Healthcare providers may have some patients repeat a BMD test after one year. In some cases, healthcare providers will also use lab tests to see if patients are losing bone faster than normal. While there is no easy way to measure improvement in bone structure, current research is being done on this issue.

For some people, an osteoporosis medication doesn't work as well when they have a disease or condition that causes bone loss. Some examples are vitamin D deficiency, celiac disease and rheumatoid arthritis. Your healthcare provider may check for diseases and conditions that can

cause bone loss before you start taking an osteoporosis medication. Or, your healthcare provider may do this if your medication is not working as it should. Sometimes treating a health problem that causes bone loss can improve your bone health.

How Long to Take an Osteoporosis Medication

At this time, healthcare providers don't know for sure how long most osteoporosis medications stay safe and effective to take. They also don't know how long these medicines continue to be helpful after you stop taking them. Research suggests that the benefits of bisphosphonate medications may continue for several years or longer after you stop taking them. This is because these medications stay in the bone for a long time.

There have been no studies on any of the osteoporosis medications that have lasted more than 10 years. Longer research studies are needed on all of the osteoporosis medicines to improve our understanding of the safety and benefits of using these medications over a period of many years.

Reviewing your Treatment Plan

If you take an osteoporosis medication, you should review plan every year with your healthcare provider. If you have been taking an osteoporosis medicine for five years, discuss the benefits of continuing it. People who are not at high risk of breaking a bone may be able to take a "drug holiday" after five years of means that you stop taking your osteoporosis continue to see your healthcare provider to monitor health.

If you are at high risk of breaking a bone, then you may benefit by on your osteoporosis medication. Other people may benefit from switching to a different medication. Your healthcare provider is the best person to guide you about whether you should start, continue, switch or stop an osteoporosis medication. Again, it is always important to look at both the benefits and risks of any medication when making a decision about your treatment.



What More You Can Do

In order for your medicine to work, you still need to get enough calcium, vitamin D and exercise.

Calcium. Getting enough calcium helps build strong bones when you're younger and helps keep them strong later in life. If you get the recommended amount of calcium from the foods you eat, you don't need to take a calcium supplement. If you are not sure, talk to your healthcare provider to find out if you need to take a calcium supplement and how much to take.

Vitamin D. Your body needs vitamin D to absorb calcium. You can get small amounts of vitamin D from a few foods. You can also get vitamin D from the sun, but you need to protect your skin from too much sun. Many people need to take a supplement. Ask your healthcare provider if you're getting enough vitamin D and whether you should have a simple blood test to check your vitamin D level.

Exercise. Your bones get stronger when you make them work. People who are bedridden or do not exercise are at high risk for osteoporosis. You should exercise about 30 minutes on most days of the week. The two types of exercise that help keep your bones strong and healthy include:

- **Weight-bearing exercises.** Examples are walking, dancing, hiking, jogging, elliptical training machines and aerobics.
- **Muscle-strengthening exercises.** Examples are lifting weights, using elastic exercise bands and using weight machines.

Check with your healthcare provider before beginning a new exercise program. If you have osteoporosis or an increased chance of breaking a bone, your healthcare provider may also recommend that you see a physical therapist. A physical therapist can teach you safe ways to move and exercise.

Adults under age 50 need
1,000 mg of calcium and 400-800
IU of vitamin D every day.

**Dr. Paul Miller recommends that
adults over age 50**
take 1,500 – 2,000 mg of calcium
and 1,000 – 2,000 IU of vitamin D

Companies That Make Osteoporosis Medicines		
Generic (Brand Name)	Company and Phone Number	FDA Approval Date
Alendronate (Fosamax, Fosamax Plus D)	Merck (800) 6+72-6372	1995
Calcitonin (Fortical, Miacalcin)	Fortical Nasal Spray Upsher-Smith (800)654-2299	2005
	Miacalcin Nasal Spray Or Injection Novartis (888) 669-6682	1995
Estrogen Therapy (ET) And Hormone Therapy (HT) Multiple brand names are available. For example: ET – Estrace and Premarin HT – FemHrt and Prempro	Too many to provide complete list. Talk to your pharmacist to get information on a specific brand.	
Ibandronate (Boniva)	Roche (800) 526-6367	2005- Monthly Oral Dose 2006 – Quarterly IV Dose
Raloxifene Evista	Eli Lilly (800) 545-5979	1997
Risedronate (Actonel, Actonel with Calcium)	Procter & Gamble (800)448-4878	2000
Teriparatide (Forteo)	Eli Lilly (800)545-5979	2002
Zoledronic Acid (Reclast)	Novartis (888) 669-6682	2007

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